Agency also noted that the organization that conducts the BA or BE study is responsible for retaining the reserve samples to eliminate potential sample substitution by the study sponsor and/or drug manufacturer and alteration of any reserve samples from a study before release of drug product samples to FDA.

FDA has observed a number of concerning handling and retention practices upon inspections of clinical and analytical sites that perform BA and BE studies for study sponsors and/or drug manufacturers seeking approval of drug products under NDAs and ANDAs. Based on this experience, FDA is updating and clarifying our recommendations for applicants of NDAs and ANDAs, including supplemental applications, and CROs regarding the procedures related to the handling and retention of reserve samples from relevant BA and BE studies, as required by §§ 320.38 and 320.63. In the context of §§ 320.38 and 320.63, the term applicant includes, as appropriate, study sponsor and/or drug manufacturer and the term CRO refers to any party contracted to help conduct BA or BE testing, including, as appropriate, site management organizations, investigators, and testing sites. Specifically, the guidance highlights: (1) how the T and RS for BA and BE studies should be distributed to the testing sites, (2) how testing sites should randomly select samples for testing and material to maintain as reserve samples, and (3) how the reserve samples should be retained. Examples of typical roles of each stakeholder for the handling and retention of reserve samples in various study settings are also discussed in the guidance.

In response to comments received to the August 2020 Compliance Policy, the Agency has updated its policy on the conditions under which FDA generally does not intend to enforce the quantity requirement at § 320.38(c) (to retain reserve samples of sufficient quantity to permit FDA to perform five times all the release tests required in an application or supplemental application) to reduce further the recommended minimum quantity of reserve samples to be retained. The additional reduction in the recommended minimum quantity described in this guidance relative to what was described in the August 2020 Compliance Policy is reflective of adjustments made to the Agency's procedures to accommodate continued concerns from industry, particularly for studies involving multiple shipments to multiple testing sites, regarding the ability to retain a sufficient quantity of reserve samples.

FDA has determined that, using the Agency's current testing methodology, the updated recommended minimum quantities of reserve samples described in this guidance are sufficient for FDA to conduct the necessary testing of the T and RS samples used in a BA or BE study as intended by the regulation. Accordingly, at this time and based on FDA's current understanding of the risks involved, FDA generally does not intend to enforce the requirement to retain a sufficient quantity to perform five times all the release tests required in the application or supplemental application, so long as the recommended lower quantities in this guidance are retained. This compliance policy is applicable to all reserve samples for BA and BE studies held to date, including reserve samples from previously completed BA or BE studies.

This guidance is being issued consistent with FDA's GGP regulation (§ 10.115). The draft portion of the guidance, when finalized, will represent the current thinking of FDA on ''Handling and Retention of BA and BE Testing Samples.'' A guidance does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug products have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in part 320 for ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans'' have been approved under OMB control number 0910–0672. The recordkeeping requirement for current good manufacturing practice sample retention in 21 CFR 211.170 has been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: March 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06500 Filed 3–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cattle Materials Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 26, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0627. The title of this information collection is ''Cattle Materials Prohibited From Use in Animal Food or Feed.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cattle Materials Prohibited From Use in Animal Food or Feed

OMB Control Number 0910–0627—Extension

This information collection helps to support implementation of section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342(a)(5)), which governs substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. Our regulation at § 589.2001 (21 CFR 589.2001) is designed to safeguard against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as ''cattle materials prohibited in animal feed'' or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements to maintain adequate written procedures and recordkeeping on renderers that receive, manufacture, process, blend, or distribute raw material from cattle and to make these records available for inspection and copying by FDA to demonstrate they are taking measures to ensure that CMPAF is not introduced into animal feed.

Under § 589.2001(f), we may designate a country from which cattle materials are not considered CMPAF. A country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine, including certain required information. We use the information provided to determine whether to grant a request for designation and to impose conditions if a request is granted. Additionally, designated countries will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries at any time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country's designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate.

The reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Description of Respondents: Respondents to this information collection are foreign governments seeking designation under § 589.2001(f) and private sector rendering facilities that process cattle materials under § 589.2001(c).

In the **Federal Register** of October 12, 2023 (88 FR 70676), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although three comments were received, the comments were not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
589.2001(f); Request for designation by FDA for exemption from requirements of this regulation and response to request for review by FDA	1	2	2	33	66

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the last renewal, we reduced the request for designation average burden per response by 40 hours (from 80 hours to 40 hours). We take this reduction because foreign governments are required to provide this information to other entities in order to comply with international standards and therefore will have already compiled the necessary information. The average burden per response to a request for review by FDA remains the same (26 hours). The burden we attribute to reporting activities is assumed to be distributed among the individual elements of the information collection activities.

Since the effective date of the regulations in 2009, only two requests for designation have been received; however, we retain our current estimate of one respondent to permit such requests for designation by respondents and also to permit related responses to FDA.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2001(c)(2)(ii), 589.2001(c)(2)(vi), and (c)(3)(i), and 589.2001(c)(3)(i)(A) and (B); Rendering facilities maintain written procedures and records, and certification or documentation from the supplier	145	1	145	45	6,525

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 reflects an adjustment decrease in our recordkeeping burden estimate, based primarily on consolidation within the industry and the related decrease in the estimated number of respondents subject to recordkeeping requirements. The burden we attribute to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents. The total number of recordkeepers contains a

subset of 50 recordkeepers who maintain written procedures and records specifically required by § 589.2001(c).

Based on our review since the last OMB approval, there is an overall adjustment decrease of 2,565 burden hours. The adjustment is attributable to decreases in the average reporting burden time and in respondents subject to recordkeeping requirements.

Dated: March 21, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06438 Filed 3–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: June 3, 2024.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Report of Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Pamela Gilden, Branch Chief, Science Planning and Operations Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, MSC 9831, Rockville, MD 20852–9831, 301–594–9954, *pamela.gilden@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 21, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06461 Filed 3–26–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

A portion of the meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Allergy and Infectious Diseases Council.

Date: June 3, 2024.

Open: 10:30 a.m. to 11:30 a.m.

Agenda: Report of Institute Director.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20852 (Hybrid Meeting).

Closed: 11:45 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40B, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council; Microbiology and Infectious Diseases Subcommittee.

Date: June 3, 2024.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 2, Rockville, MD 20852 (Hybrid Meeting).

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 2, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40B Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council; Immunology and Transplantation Subcommittee.

Date: June 3, 2024.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 1, Rockville, MD 20852 (Hybrid Meeting).

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 1, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institutes of Health, NIAID, National Institutes of Health, 5601 Fishers Lane, Room 3F40B, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council; Acquired Immunodeficiency Syndrome Subcommittee.

Date: June 3, 2024.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20852 (Hybrid Meeting).

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Grand Hall, 5601 Fishers Lane, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F40B, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov.*